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**MEMO ENDORSED**

Anthony J. Viola  
 Andre K. Cizmarik  
 EDWARDS ANGELL PALMER & DODGE LLP  
 Attorneys for Plaintiffs  
 Takeda Pharmaceutical Company Limited, and  
 Takeda Pharmaceuticals North America, Inc.  
 750 Lexington Ave.  
 New York, NY 10022  
 (212) 308-4411

USDC SDNY  
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**UNITED STATES DISTRICT COURT  
 SOUTHERN DISTRICT OF NEW YORK**

Takeda Pharmaceutical Company Limited and  
 Takeda Pharmaceuticals North America, Inc.,

Civil Action No. 09 CIV 6051 (DLC)

Plaintiffs,

v.

Torrent Pharmaceuticals Limited and  
 Torrent Pharma Inc.,

Defendants.

**STIPULATION REGARDING CONFIDENTIALITY  
AND  
PROTECTIVE ORDER**

All parties to the above-referenced action, by their attorneys, hereby stipulate and agree that the terms and conditions of this Stipulation Regarding Confidentiality And Protective Order (“Stipulation”) shall govern the production and handling of documents, answers to interrogatories, responses to requests for admissions, depositions, pleadings, exhibits, and all other exchanges of information by the parties in this action.

Pursuant to Fed. R. Civ. P. 26(c), by agreement of the parties, the Court finds that good

cause exists for entry of a protective order to prevent unauthorized disclosure and use of the parties' trade secrets and other confidential information during and after the course of this litigation. This protective order shall apply to all documents produced during the course of this litigation. Accordingly, IT IS HEREBY ORDERED THAT:

1. "Confidential Material" is defined as all documents, information, testimony or things produced during discovery which a party (i) believes contain sensitive trade secrets, proprietary information, or other confidential information (including but not limited to non-public information concerning research, development, testing, or evaluation of pharmaceuticals, non-public patent applications and files, non-public manufacturing, marketing, or financial information, non-public license agreements or negotiations, non-public information concerning drug applications, and non-public communications with the Food and Drug Administration) that can be the subject of protection pursuant to Federal Rule of Civil Procedure 26(c), and (ii) designates as such, in accordance with the procedures set forth in paragraph 7. In the case of Confidential Material that is so extremely sensitive in the context of this case that there is a real danger that the party producing the information could be prejudiced if the information is disclosed under the protection provided by Confidential Material, a party may designate such material as "Highly Confidential - Outside Attorneys Eyes Only Material." As used herein, the designation "Highly Confidential-Outside Attorneys Eyes Only" may be invoked in good faith by a Producing Party and only with respect to particularly sensitive marketing, sales, technical and financial information, including, by way of

example but not of limitation, customer lists, price lists, costs of production, financial projections or profit calculations, trade secrets, and information related to research and development. In appropriate cases, sensitive third party information may be so designated. The designation "Confidential" may be invoked in good faith by a Producing Party with respect to any other Confidential Material.

2. Confidential Material and Highly Confidential - Outside Attorneys Eyes Only Material shall be used by the parties solely for the prosecution or defense of the claims and counterclaims asserted in the pending proceedings between the parties. No Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material disclosed in this action may under any circumstances be disclosed or disseminated to non-parties, except as provided herein, and the parties and recipients shall not use Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material disclosed by another party in the conduct of their business or for any reason other than the purposes of the pending proceedings between the parties.
3. Except with the prior written consent of the producer, or in accordance with the procedure set forth in paragraph 9, Confidential Material may be disclosed only to the following persons and to no others, including without limitation government agencies or investigating bodies, except pursuant to lawful process, reasonable advance notice of which is to be provided to the party designating such material as Confidential:

(a) Any “outside” attorneys working on this action and their respective associates, paralegals, clerks, and employees involved in the conduct of this litigation; and up to four designated in-house attorneys or intellectual property professionals<sup>1</sup> or regulatory affairs professional<sup>2</sup>. Outside attorneys are those attorneys employed by the firms of record, including any contract attorneys, even if such attorneys are not otherwise identified specifically on pleadings and who are U.S. attorneys. Persons working on development of business plans related to, or patent applications related to pioglitazone-containing drug products or methods of using same are excluded from seeing Confidential Material, and persons who do have access to Confidential Material cannot participate in such activities for five years after this case is finally terminated. The term “business plan” does not encompass settlement agreements. Designated in-house attorneys are currently identified as follows:

*For Takeda plaintiffs:*

Ken Greisman, Senior Vice President, General Counsel & Secretary  
Takeda Pharmaceuticals North America, Inc.

George Kokkines, Associate General Counsel, Litigation and Compliance  
Takeda Pharmaceuticals North America, Inc.

Atsuhiro Inaba, Manager, Litigation and Dispute Resolution  
Takeda Pharmaceutical Company Limited

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<sup>1</sup> “Intellectual property professionals” shall refer to Japanese intellectual property professionals trained in intellectual property whose primary responsibilities include tasks typically performed by lawyers in the United States, including, e.g., litigation management, prosecution, and licensing.

<sup>2</sup> “Regulatory affairs professionals” shall refer to persons whose primary responsibilities are correspondence and submission to the Food and Drug Administration with respect to prescription drug products, that may include pioglitazone, but having no responsibilities with respect to patent applications or development of business plans related to pioglitazone.

Tadaaki Kitao, Senior Manager, Litigation and Dispute Resolution  
Takeda Pharmaceutical Company Limited

*For Torrent defendants.:*

Susan Perry, Regulatory Affairs Manager, Torrent Pharma, Inc.

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If a party wishes to amend the list of designated attorneys in this paragraph, the designating party shall give notice to all parties. The notified parties shall have seven (7) calendar days to object to any designation. In the event of an objection, the parties shall promptly confer in good faith to resolve the concerns giving rise to the objection. If the parties are unable to reach agreement regarding such designation, the objecting party must apply to the Court for resolution. The foregoing seven (7) calendar day period may be extended or shortened by agreement of the parties or by Order of the Court.

- (b) Vendors retained by counsel to translate, copy, image, catalog, or otherwise prepare or organize documents or things. For purposes of this Stipulation, the phrase "vendors retained by counsel" shall not include any officer, director, or employee of a party, or any person regularly employed by a party;
- (c) Up to three (3) persons selected from the officers, directors and employees of the receiving party. Persons working on development of, business plans related to, or patent applications related to pioglitazone-

containing drug products or methods of using same are excluded from seeing Confidential Material, and persons who do have access to Confidential Material cannot participate in such activities for five years after this case is finally terminated;

- (d) Outside experts and consultants retained by a party or the party's counsel for the purpose of preparing or assisting in this litigation, and their respective clerks and employees involved in assisting them in this litigation, to the extent deemed necessary by counsel. Disclosure to an outside experts or consultant, however, shall be subject to the terms of paragraph 6 below;
- (e) The finders of fact, their assistants, court reporters and similar personnel involved in the pending proceedings between the parties;
- (f) [DELETED];
- (g) Any person indicated on the face of the document to be its originator or author or a recipient thereof, and any deponent or witness who, based on foundation testimony or other discovery, is shown to be the document's originator or author or a recipient thereof, or who the deposing party otherwise believes has personally seen the document or has knowledge concerning its contents. If in fact the witness has not seen the document and does not have knowledge concerning its contents, examination concerning that document shall cease; and

- (h) Any other person, either with the prior written consent of the party who has designated such information as Confidential or pursuant to an order of the Court.
- 4. Except with the prior written consent of the producer, or in accordance with the procedure set forth in paragraph 9, Highly Confidential - Outside Attorneys Eyes Only Material may be disclosed only to the following persons and to no others, including without limitation government agencies or investigating bodies, except pursuant to lawful process, reasonable advance notice of which is to be provided to the party designating such material as confidential:
  - (a) The outside counsel of record in this proceeding, including their respective associates, paralegals, clerks, and employees involved in the conduct of this litigation. For purposes of this Stipulation, the phrase "outside counsel of record" shall not include any officer, director, or employee of a party, or any person regularly employed by a party;
  - (b) Vendors retained by counsel to translate, copy, image, catalog, or otherwise prepare or organize documents or things. For purposes of this Stipulation, the phrase "vendors retained by counsel" shall not include any officer, director, or employee of a party, or any person regularly employed by a party;
  - (c) Outside experts and consultants retained by outside counsel of record for the purpose of preparing or assisting in this litigation, and their respective clerks and employees involved in assisting them in this litigation, to the extent deemed necessary by counsel. For purposes of this Stipulation,

the phrase "outside experts and consultants" shall not include any officer, director, or employee of a party, or any person regularly employed, retained, or otherwise consulted by a party on matters not pertaining to this litigation. Disclosure to an outside experts or consultant, however, shall be subject to the terms of paragraph 6 below;

- (d) The finders of fact, their assistants, court reporters and similar personnel involved in the pending proceedings between the parties;
- (e) [DELETED];
- (f) Any person indicated on the face of the document to be its originator or author or a recipient thereof, and any deponent or witness who, based on foundation testimony or other discovery, is shown to be the document's originator or author or a recipient thereof, or who the deposing party otherwise believes has personally seen the document or has knowledge concerning its contents. If in fact the witness has not seen the document and does not have knowledge concerning its contents, examination concerning that document shall cease; and
- (g) Any other person, either with the prior written consent of the party who has designated such information as Highly Confidential or pursuant to an order of the Court.

5. Except for vendors of copying, imaging, cataloging or other document preparation services, the persons described in paragraphs 3(b), (c), (d), (f), (g) and (h) shall have access to the Confidential Material, and the persons described in paragraphs 4(b), (c), (e), (f) and (g) shall have access to Highly Confidential -

Outside Attorneys Eyes Only Material only after they have been made aware of the provisions of this Stipulation and have manifested their assent to be bound thereby by signing a copy of the Statement annexed hereto as Exhibit A.

Executed copies of the Statements shall be maintained by the attorney who discloses Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material to the signatory. Nothing in this Stipulation shall be construed to require execution of the Statement by the party producing and designating such Confidential Material, or to prevent disclosure of Confidential Material by the party producing and designating such Confidential Material, except as otherwise provided in paragraphs 3(f) and 4(e).

6. Before disclosing Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material to an outside expert or consultant pursuant to paragraphs 3(d) or 4(c) above, the party retaining the expert or consultant shall provide the other party with a copy of the Statement executed by the expert or consultant, a curriculum vitae or current resume of the expert or consultant, and full disclosure of such person's past or present relationship or affiliation with any party (collectively, the "Background Information"). Within twenty (20) business days of the receipt of such Background Information, any party may object in writing to the expert or consultant having access to Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material. Failure to object within such period shall be deemed approval. If the parties are unable to reach agreement within twenty-five (25) business days after receipt of such Background Information, the party seeking to disclose Confidential Material or

Highly Confidential - Outside Attorneys Eyes Only Material may seek an order granting the expert or consultant access to such materials. No disclosure shall be made to any expert or consultant prior to approval by the producing party or an order of the Court granting access.

7. The parties shall designate Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material as follows:
  - (a) In the case of documents, designation shall be made by placing the following legend on each page of any such document prior to production: "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS EYES ONLY" or similar legend identifying material as Confidential or Highly Confidential - Outside Attorneys Eyes Only.
  - (b) In the case of depositions, counsel for any party, or any deponent in this action, who in good faith reasonably believes that any portion of his, her, or its testimony discloses any sensitive information of a nonpublic nature, may designate such portions as Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material by advising the reporter of the designation. The reporter shall designate the portion of the transcript (including exhibits) which contains Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material by placing the legend "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS EYES ONLY" on each page of the transcript containing such material and shall separately bind such portions of the

transcript indicating that Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material is contained therein.

(c) Any party may designate documents used at depositions or portions of deposition transcripts as containing Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material even if not initially marked as such in accordance with the terms of this Stipulation by so advising counsel for each party in writing within thirty (30) days of the receipt of the document or deposition transcript which he, she, or it wishes to designate as Confidential or Highly Confidential - Outside Attorneys Eyes Only. Thereafter each such document or transcript portion shall be treated in accordance with the terms of this Stipulation. Any person served with written notice of any such designation of previously produced documents or deposition transcripts as containing Confidential Material shall thereafter treat such information as if it had been designated as Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material at the time he, she, or it first received it in connection with this action and shall mark all copies of such documents in his, her, or its possession accordingly.

(d) In the event that third parties produce documents or provide information, including deposition testimony, in connection with the parties' court proceeding, the parties to this proceeding agree that production of such documents or information shall be made subject to the provisions of this Stipulation, and that the third parties producing such documents and

information shall be treated as producing parties within the terms of this Stipulation.

8. Any pages in a written submission to the Court that disclose Confidential Material shall be marked according to paragraph 7 and shall be filed under seal, after making the appropriate motion and receiving the Court's consent pursuant to Electronic Case Filing Rule 6.2. The original and all copies of any document constituting or containing Confidential Material shall state in bold letters on the first page of the document that it is CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE ATTORNEYS EYES ONLY.
9. A party shall not be obligated to challenge the propriety of a Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material designation made by another party at the time it is made, and failure to do so shall not preclude a subsequent challenge thereto. A party may challenge such designation by sending written notice to the designating party. The parties shall attempt to resolve any challenge in good faith on an informal basis. If the challenge cannot be resolved in that manner, either party may apply for an appropriate ruling from the Court. In the event that a party challenges such designation, such party shall provide to the other party reasonable prior written notice of its motion or application. The burden of proving that information has been properly designated as Confidential or Highly Confidential – Outside Attorneys Eyes Only shall be on the Producing Party making such designation.
10. The disclosure by a producing party of Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material, by way of delivering

responses to discovery requests, delivering copies of documents, disclosing deposition testimony or otherwise, without the designation required by paragraph 7, shall constitute a waiver of any claim of confidentiality, except in the situation where (a) such disclosure resulted from inadvertence or mistake on the part of the producing party, (b) such inadvertent or mistaken disclosure has been brought to the attention of the receiving party promptly after discovery of such disclosure but not later than fourteen (14) days after such discovery, and (c) within fourteen (14) days of such discovery, the producing party has provided properly marked documents. Upon such notice, and upon receipt of properly marked documents, the materials shall be treated as if originally produced pursuant to this Stipulation and the receiving party shall return said unmarked documents and things to the extent practicable, and shall not retain copies thereof and shall treat information contained in said documents and things and any summaries or notes thereof as if originally produced pursuant to this Stipulation.

11. If information subject to a claim of attorney-client privilege or work product immunity is inadvertently or mistakenly produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or work-product immunity for such information. If a party has inadvertently or mistakenly produced information subject to claim of immunity or privilege, upon request made by the producing party within seven (7) business days of its discovery that such inadvertent or mistaken production has occurred, the information for which a claim of inadvertent production is made shall be

returned within seven (7) business days of such request, and all copies of any returned document that may have been made shall be destroyed. The party returning such information may move the Court for an order compelling production of such information if it believes that the information is not properly being withheld on the basis of the attorney-client privilege or work product doctrine. If the receiving party does not return the documents within seven (7) business days of such request by the producing party, the producing party may request that the Court issue an order compelling the return or destruction of all copies of the inadvertently or mistakenly produced information or document.

12. In the event that Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material is used in any court hearing or other proceeding, it shall not lose its Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material status through such use, and the parties shall take all steps reasonably required to protect its confidentiality during such use.
13. Counsel for either party shall have the right to exclude from depositions any person, other than the deponent and the court reporter, who is not authorized under this Protective Order to receive Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material. Such exclusion shall be applicable only during periods of examination or testimony directed to or comprising information which has been designated as Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material.
14. Within sixty (60) days of the termination of the pending proceedings between the parties, each party shall return all Confidential Material or Highly Confidential -

Outside Attorneys Eyes Only Material and all copies thereof to the party which produced it or shall confirm in writing to the producing party that all such documents have been destroyed, except that counsel shall be permitted to retain copies of documents filed with the Court, transcripts, and attorney work product which shall remain subject to this Order.

15. By this Stipulation, no person waives any right it may have to object to any or all discovery requests on any applicable grounds or to object to the admission on any applicable grounds of any discovery materials as evidence at any trial or hearing. In any proceeding concerning the confidential and proprietary nature of discovery material a party is seeking to protect from disclosure, the parties shall not use production under this Stipulation as ground for an argument that such discovery material is not confidential or proprietary.
16. The provisions of this Stipulation may be modified or supplemented by agreement of the parties hereto only in writing. Each party hereto reserves the right to apply to the Court for protection pursuant to, relief from any or all of the provisions of, or protection in addition to that provided by, this Stipulation. Absent written permission of the party disclosing the Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material, or order of the Court, the provisions of this Stipulation shall continue to be binding after the conclusion of this action.
17. To the extent that any discovery material has been produced by any party prior to the entry of this Stipulation, the party producing such material may retroactively designate such material as Confidential Material or Highly Confidential -

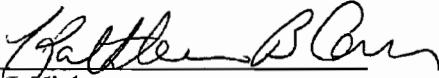
Outside Attorneys Eyes Only Material by placing the appropriate legend on such material and providing copies of the material bearing such legends to the other party to replace non-designated copies of the material previously produced. Any document already produced which bears such a legend shall be deemed produced pursuant to this Stipulation.

18. Nothing in this Stipulation shall prevent or otherwise restrict any counsel from rendering advice to his or her client and, in the course thereof, relying generally on his or her examination of documents designated Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material, provided, however, that in rendering such advice and otherwise communicating with such client, counsel shall not make specific disclosure of the contents of any document so designated. Except as otherwise provided herein, nothing in this Order shall be deemed a waiver of any right any party otherwise might have under the Federal Rules of Civil Procedure or the doctrines of attorney-client privilege or attorney work product privilege.
19. In the event a party has legally obtained documents or information through a method other than production pursuant to this Stipulation, nothing in this Stipulation shall limit the use by that party of such documents or information, even if copies of such documents or information have been designated as Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material by another party.

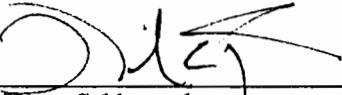
This stipulation binds the parties to treat as confidential the documents so classified. The Court, however, has not reviewed the documents referenced herein; therefore, by so ordering this stipulation, the Court makes no finding as to whether the documents are confidential. That finding will be made, if ever, upon a document-by-document review. Moreover, the Court does NOT so order ~~which purports to authorize the parties to file documents under seal without a prior court order.~~

*S. andread.*  
*Frances Lake*  
*8/27/09*

Dated:

  
Anthony J. Viola  
Andre K. Cizmarik  
Joseph E. Czerniawski  
EDWARDS ANGELL PALMER & DODGE LLP  
Attorneys for Plaintiffs  
Takeda Pharmaceutical Company Limited,  
Takeda Pharmaceuticals North America, Inc. and  
Takeda Global Research & Development Center,  
Inc.  
750 Lexington Avenue  
New York, NY 10022  
(212) 308-4411

David G. Conlin (admitted pro hac vice)  
Barbara L. Moore (admitted pro hac vice)  
Kathleen B. Carr (admitted pro hac vice)  
Christopher P. Silva (admitted pro hac vice)  
Adam P. Samansky (admitted pro hac vice)  
EDWARDS ANGELL PALMER & DODGE LLP  
111 Huntington Avenue  
Boston, MA 02199-7613  
(617) 239-0100

  
H. Keeto Sabharwal  
Daniel E. Yonan (to be admitted pro hac vice)  
BLANK ROME LLP  
Attorneys for Defendants  
Torrent Pharmaceuticals Limited, and Torrent  
Pharma Inc.  
Watergate  
600 New Hampshire Avenue NW  
Washington, DC 20037  
(202) 772-5932

Dennies Varughese (to be admitted pro hac vice)  
BLANK ROME LLP  
One Logan Square  
130 North 18th Street  
Philadelphia, PA 19103-6998  
(215) 569-5500

SO ORDERED.

  
United States District Judge

Dated: \_\_\_\_\_, 2009

**Exhibit A**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

Takeda Pharmaceutical Company Limited and  
Takeda Pharmaceuticals North America, Inc.,

Civil Action No. 09 CIV 6051 (DLC)

Plaintiffs,

v.

Torrent Pharmaceuticals Limited and  
Torrent Pharma Inc.,

Defendants.

**ACKNOWLEDGMENT OF CONFIDENTIALITY STATEMENT**

The undersigned hereby acknowledges that he or she has read the Stipulation Regarding Confidentiality And Protective Order dated \_\_\_\_\_ annexed hereto ("Stipulation"), and agrees that, with respect to any material disclosed to the undersigned which has been specifically designated as Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material, and all information contained therein, he or she shall maintain such material in strict confidence and shall not disclose such material or information to any other person, except in accordance with the terms of the Stipulation. The undersigned agrees that by its signature below, the undersigned intends to make a binding agreement with the parties to the above-captioned proceeding to treat all Confidential Material and Highly Confidential - Outside Attorneys Eyes Only Material in accordance with the Stipulation, and not to use the Confidential Material or Highly Confidential - Outside Attorneys Eyes Only Material, or the

information they contain, for any purpose other than for the prosecution or defense of the claims or counterclaims asserted in the pending proceedings between the parties. The undersigned agrees that either party may bring an action to enforce compliance with this agreement and/or seek damages for any violation of this agreement, and further agrees to submit to the jurisdiction of the United States District Court for the Southern District of New York or any court of competent jurisdiction for the purpose of such an action.

Dated: \_\_\_\_\_

(signature)

Print name and address:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_